# Improving Public Health:
## Promoting Safe and Effective Drug Use

The FDA's **Center for Drug Evaluation and Research** (CDER) promotes and protects the health of Americans by assuring that all prescription and over-the-counter drugs are **safe and effective.** CDER evaluates all new drugs before they are sold, and serves as a consumer watchdog for the more than 10,000 drugs on the market to be sure they continue to meet the **highest standards.** The center routinely monitors TV, radio, and print **drug ads** to ensure they are truthful and balanced. CDER also plays a critical role in providing health professionals and **consumers information** to use drugs appropriately and safely. Recent drug approvals represent important advances for children, women, elderly persons, and patients with heart disease and cancer, leading causes of death in the United States. CDER priorities include:

### Assuring that safe and effective new and generic drugs are available to the American public

- CDER's multidisciplinary scientific staff conducts thorough reviews of all **new and generic drugs.**
- FDA has **reduced** the average review time for new drugs covered under the Prescription Drug User Fee Act (PDUFA) from more than 2.5 years to less than one year.
- Patients with life-threatening illnesses gain access to treatments **sooner.**
- FDA requires many drug manufacturers to provide information on how **children** can take their drugs safely and effectively.
- As part of the Nation's counter-terrorism efforts, the FDA is encouraging the development and expediting the review of medications for the prevention or treatment of injuries that could be caused by **terrorists** using biological, chemical or nuclear agents.

### Improving drug safety

- After approval, CDER identifies drug safety concerns through voluntary reports submitted to the FDA's **MedWatch** program and the center's adverse event reporting system, which together receive more than 250,000 reports each year.
- CDER scientists analyze **adverse event reports** and take actions that best protect the public's health, ranging from providing more information to patients to withdrawing drugs from the marketplace.
- CDER has instituted a comprehensive program to communicate with consumers and improve patient safety. For example, 6 million consumers received FDA's brochure on **proper medication** use.
- FDA works with industry to reduce errors related to confusing packaging and/or drug names.
- FDA has proposed a regulation to make prescription drug labeling easier for health-care providers to use.

### Year 2001 Drug Approvals

In 2001, CDER approved 66 new drugs, 24 of which were new molecular entities with ingredients never before marketed in the United States. Ten of the new drugs received priority status in recognition of their special importance for the public health. One of these drugs was Gleevec, a new oral treatment for chronic myeloid leukemia, a rare life-threatening form of cancer, which the FDA approved in the record time of 2.5 months. The rest of the priority drugs were approved within 6 months.

**For more information**, please contact CDER at 301-827-4573, or visit the FDA Web site at *www.fda.gov/cder.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
Office of Public Affairs
5600 Fishers Lane
Rockville, MD 20857

Publication No. FS 01-3
FDA Web site: *www.fda.gov*
Revised: February 2002